

Application Serial No.: 10/039,876
Amendment dated: January 5, 2006
Response to Office Action dated: July 5, 2005

Amendments to the Drawings:

The attached REPLACEMENT SHEET of drawings includes changes to what was formerly listed as the "FIGURE". This sheet, which includes "FIGURE 1" replaces the original sheet. The title of "FIGURE" has been amended read "FIGURE 1".

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Remarks:

Reconsideration of the application in view of the above amendments and following remarks is requested. Claims 41-53 are now in the case. Claims 1-31 and 34 has/have been canceled. Claims 32, 33, and 35-40 have been withdrawn.

I) Amendment to the Drawings

The Drawings were objected to because the Office Action required the "FIGURE" to be re-labeled as "FIGURE 1". A Replacement Sheet of the drawings is submitted herewith.

II) Amendments to the Specification

A) Amendments to be consistent with the required correction to the drawings:

The above-mentioned amendment to the drawing required amendments to pages 6, 13, and 14 of the specification to amend recitations of "FIGURE" to "FIGURE 1".

B) Amendment to correct an address:

The paragraph beginning at line 13 of page 88 has been amended to recite the correct address for the American Type Culture Collection.

C) Amendment to remove hyperlinks:

Paragraphs on pages 72, 86 and 87 have been amended to remove hyperlinks.

III) Rejections under 35 U.S.C. § 112

Claims 22-29 were rejected under 35 U.S.C. § 112 as being indefinite because the Office Action states that "it is not clear what polynucleotide sequence is contained on 21q22.3 region of human chromosome 21 to which the isolated polynucleotide hybridizes" and the Office Action suggested that "the 21q22.3 region of human chromosome 21 be identified by SEQ ID NO: to overcome the rejection." This rejection is made of claims 22 and 27 as the independent claims, with claims 23-26 and 28-29 being rejected as depending from indefinite base claims.

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Claims 22-29 have been canceled in this Amendment. However, since the chromosome 21q22.3 region is recited in new claim 53, in the interest of expedited prosecution, Applicants address this rejection herein. Applicants respectfully traverse this rejection. A person skilled in the art of cytogenetics would know that the region of human chromosome 21 is readily recognizable from the designation, "21q22.3". Thus, "21" is the chromosome, "q" is the arm of the chromosome, "22" is the region, and ".3" is the subregion. Thus, Applicants have already provided the "region of human chromosome 21" as suggested in the Office Action. Applicants respectfully request this rejection be withdrawn.

IV) Rejections under 35 U.S.C. § 101 and 112, paragraph 1

Claims 22-31 and 34 were rejected under 35 U.S.C. § 101 because the Office Action states that they are not supported by either a specific and substantial asserted utility or a well established utility. The Office Action asserts that the polypeptides of the present invention lack a specific, substantial, and credible utility as cytokines. The Office Action further alleges that the claims do not comply with the first paragraph of 35 U.S.C. § 112 on the basis of a rejection under 35 U.S.C. § 101.

Note: On page 23, line 16, the Office Action recites "PRO1885 variants", and on page 11, line 11, the Office Action recites the "TNFRL family". Applicants believe these recitations in the Office Action are inadvertent typographical errors.

Claims 22-31 and 34 have been canceled herein. As such these rejections should properly be withdrawn.

V) Rejection base on Double Patenting.

Claims 22-31 were rejected as not being patently distinct over the claims 1-6 of U.S. Patent No. 6388064, to which the instant patent application claims priority.

The Office Action further states:

"The claims are also not patentably distinct from each other because they both disclose a vector comprising said polynucleotide comprising operably linked elements and cell comprising said vector isolated polynucleotide encoding a polypeptide the disclosed in a virus particle displaying a heterologous fusion protein on the outer surface thereof. The common feature of claim 53 of instant application and claims 11-18 of Patent 5,837,500 is the concept of

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displaying a chimeric of fusion binding protein on the surface of a genetic package, for example a phage."

Claims 22-31 if the instant application are canceled. As such, this rejection no longer stands. However, in the interests of being fully responsive, Applicants address the quoted paragraph above. Applicants respectfully suggest that the language of the quoted paragraph does not apply to the examination of the instant application and that inclusion of this paragraph in the instant Office Action was by error. If Applicants are under the wrong impression, clarification is respectfully requested on how the present claims overlap with the claims of U.S. Patent 5,837,500.

V) Support for Newly added claims 41-53:

Support for the polynucleotide of newly added claims 41, 42, and 43 can be found, for example, on page 14, lines 4-10 wherein the specification teaches, "a mature polypeptide of 210 amino acids (residue 26 (Tyr) to residue 235 (Ser) of SEQ ID NO: 2)." One skilled in the art would know that amino acid residues 26 to 235 of SEQ ID NO:2 correspond to the polynucleotide from nucleotide 194 to nucleotide 823 of SEQ ID NO: 1. Furthermore, the polynucleotide from nucleotide 194 to nucleotide 823 is recited on line 23-25 of page 2. The hybridization wash conditions are taught on page 20, lines 24-28. Additional support for the recitation a polypeptide from nucleotide 119 to nucleotide 823 can be found on page 2, lines 25-28, as well as that one skilled in the art would know that amino acid residues 1 to 235 of SEQ ID NO: 2 correspond to the polynucleotide from nucleotide 119 to 823 of SEQ ID NO: 1.

Support for the vector of claim 44 can be found throughout the specification. In addition, one of skill in the art would know that such vectors can be used to replicate DNA.

Support for the polynucleotide probes of claims 45-48 can be found on page 20, lines 10-31; page 71, line 36 to page 72, line 23; page 72, line 34 to page 73, line 26; and page 74, line 33 to page 75, line 9. Support for polynucleotides of claims 46, 47, and 48 can be found on page 21 from line 31 to page 22, line 10, as well as in Example 2, page 84 lines 23-29, and page 85, lines 25-28.

Support for the oligonucleotide of claims 49-51 can be found throughout the Examples as used in polymerase chain reactions. Support for oligonucleotides of between 18 and 25 base pairs in length (claim 50) can be found by looking at the lengths

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of the oligonucleotides of the SEQ ID NOs:13-17, and 19-20. These are also specifically claimed in claim 51.

Support for a polynucleotide produced by polymerase chain reaction as described in claim 52 can be found, for example, on page 23, lines 27 to 30.

Support for a polynucleotide that hybridizes to the 21q22.3 region of human chromosome 21 (claim 53) can be found, for example, on page 71, line 36 to page 72, line 23. Hybridization wash conditions of 0.1XSSC to 2XSSC, 0.1% SDS at 55°C-65°C can be found on page 20, lines 24 to 28.

Support for the utility of the polynucleotides of the newly added claims can be found on page 71, line 36 to page 73, line 26. As a polynucleotide that shows linkage to chromosome 21q22.3, the polynucleotides of the present invention can be used to detect Down Syndrome trisomy or partial trisomy. See page 73, lines 2-9. As shown in Example 3, pages 86-87, the polynucleotides of the presently claimed invention were mapped to the 21q22.3 region of human chromosome 21.

Applicants reserve the right to prosecute claims to cancelled subject matter in one or more continuing applications.

On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6752.

Respectfully Submitted,



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Enclosures:

Petition and Fee for Extension of Time (in duplicate)
Amendment Fee Transmittal (in duplicate)
Change of Address Letter